No. 15-7

In the Supreme Court of the United States

UNIVERSAL HEALTH SERVICES, INC.,
Petitioner,

v.

UNITED STATES AND MASSACHUSETTS, *ex rel.*
JULIO ESCOBAR AND CARMEN CORREA,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the First Circuit

AMICUS CURIAE BRIEF OF CARESOURCE, IN SUPPORT OF PETITIONER

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INTEREST OF *AMICUS CURIAE*

Amicus Curiae CareSource is an Ohio not-for-profit tax-exempt corporation organized and operated solely to perform, develop, and implement comprehensive healthcare services for its members.[1] CareSource's mission is to "make a lasting difference in [its] members' lives by improving their health and well-being." CareSource's mission is its "heartbeat"; it is the essence of the company and CareSource's dedication to its mission is a hallmark of its success.

CareSource is headquartered in Dayton, Ohio. It also has offices in Cleveland, Columbus, Indianapolis, and Louisville and currently has 2,500 employees. CareSource has expanded its footprint beyond Ohio, serving more than 1.4 million consumers in Ohio, Kentucky, Indiana and West Virginia, with expansion underway in Georgia.

CareSource is licensed by the State of Ohio as a health insuring corporation. The CareSource Medicaid plan, which has been in operation for 27 years, currently has approximately 1,322,155 members in the State of Ohio. CareSource has a contract with the Ohio Department of Medicaid (ODM) to provide Medicaid managed care services to Ohio's Covered Families and Children (CFC) population, which includes children up

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[1] Pursuant to Rule 37.6, no counsel for a party authored any part of this brief; no party or party's counsel made a monetary contribution intended to fund the preparation or submission of this brief; and no person other than *amicus curiae*, its members, or its counsel made a monetary contribution to the brief's preparation or submission. Letters from the parties consenting to the filing of this brief are filed with the clerk.

to age 19, pregnant women, and families with children under age 18 who meet certain income requirements. CareSource also has a contract with ODM for the Medicaid Aged Blind and Disabled (ABD) population, which includes adults age 65 and over, individuals who are legally blind, and individuals with disabilities.

CareSource also provides managed care services to individuals eligible for both Medicare and Medicaid ("dual eligibles") via Ohio's integrated care delivery system known as "MyCare Ohio." Individuals eligible for this program include adults with disabilities or certain mental illnesses and persons 65 years and older with such conditions.

CareSource also offers Affordable Care Act health plans, called "Just4Me," in four states. These plans provide affordable coverage and are marketed to low income individuals and families in Ohio, Kentucky, West Virginia, and Indiana.

All of CareSource's plans are designed to fulfill CareSource's mission of improving the health and well-being of its members. CareSource does not engage in any line of business that is not intended to fulfill this mission.

CareSource has a strong interest in the outcome of this case, as the expansion of liability under the False Claims Act (codified at 31 U.S.C. §§ 3729-3733 (2012), the "Act" or the "FCA") through the implied certification theory would make it much more difficult for CareSource, and other nonprofit healthcare providers, to address the healthcare issues facing their members. Permitting FCA liability based on implied certification of compliance will increase the number of

FCA *qui tam* lawsuits, particularly those affecting the healthcare industry, without adequate protection against abuse by whistleblowers (also called relators) or the Government. As a result, rather than expending funds on programs designed to support their members, nonprofits like CareSource, who use their resources to keep their doors open to members on a 24/7 basis, would be forced to divert those resources to defending against FCA lawsuits.

SUMMARY OF THE ARGUMENT

I. Extending FCA liability to claims involving "implied certification" would be highly problematic because unlike other types of claims that are recognized under 31 U.S.C. § 3729(a)(1)(A), implied certification claims cannot readily be identified through an objective test. The theory espoused by the Second and Sixth Circuits, that liability for implied certifications with statutes, regulations, or contractual provisions can be predicated on an express condition of payment—although somewhat better than other, more expansive theories of implied certification liability—remains hopelessly mired in subjective determinations. *Mikes v. Straus*, 274 F.3d 687 (2d Cir. 2001); *United States ex rel. Hobbs v. MedQuest Assocs., Inc.*, 711 F.3d 707 (6th Cir. 2013). This is particularly true in cases affecting the healthcare industry, which represent the majority of FCA cases.[2] For example, the issue of whether an

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[2] Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, *Justice Department Recovers Over $3.5 Billion From False Claims Act Cases in Fiscal Year 2015* (Dec. 3, 2015), *available at* http://www.justice.gov/opa/pr/justice-department-recovers-over-35-billion-false-claims-act-cases-fiscal-year-2015.

entity that receives payment through Medicaid or Medicare has failed to comply with a condition must make the distinction of whether the condition was one of participation, payment, or perhaps a combination of both. *MedQuest Assocs.*, 711 F.3d at 714, *citing United States ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1176 (9th Cir. 2006). Given the multitude of regulations and statutes that federal and state government agencies incorporate by reference into contracts for services with healthcare providers and health plans, it would be virtually impossible to create a uniform standard for implied certification of compliance regarding express conditions of payment in a contract. *See, e.g., United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1222 (10th Cir. 2008).

The theory espoused by the First Circuit is even more alarming because liability would not even require an express condition of payment in the statute, regulation, or contract, but a mere "implied condition of payment" would be sufficient. *See United States ex rel. Escobar v. Universal Health Services, Inc.*, 780 F.3d 504 (1st Cir. 2015); *United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377 (1st Cir. 2011).

The jurisprudence from other circuits which have recognized FCA liability under the implied certification theory is equally troubling. Although courts recognize that the FCA was not meant to be a "blunt instrument" of regulatory enforcement[3] and that the implied

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[3] *Mikes v. Straus*, 274 F.3d 687 (2d Cir. 2001).

certification theory is "prone to abuse,"[4] the only suggestion to protect defendants against rampant abuse and meritless suits is that strict adherence to the requirements of scienter and materiality will eliminate meritless suits. *See United States ex rel. Ebeid v. Lungwitz*, 616 F.3d 993, 998 (9th Cir.), *cert. denied*, 562 U.S. 1102 (2010); *United States v. Sci. App. Int'l Corp.*, 626 F.3d 1257 (D.C. Cir. 2010); *United States v. Triple Canopy, Inc.*, 775 F.3d 629 (4th Cir. 2015).

This reasoning is flawed. Requiring a finding of materiality and scienter in order to deem a claim "false" necessarily introduces an element of subjectivity that cannot be determined by the court but must be left to the trier of fact—thus preventing courts from dismissing meritless suits. *Cf. United States v. Sci. App. Int'l Corp.*, 626 F.3d 1257, 1269 (D.C. Cir. 2010) (stating that materiality may be established through testimony). Additionally, requiring materiality as an element to determine falsity conflates the two elements—making it more difficult for a defendant to demonstrate a claim is not false.

The injection of such subjectivity will greatly increase the risk facing defendants. These risks are of particular concern in the healthcare industry because of the plethora of Medicaid and Medicare regulations and statutes that could become the basis of an FCA claim, thereby making it nearly impossible for hospitals, health plans, physicians, and others in the industry to have adequate notice of precisely what actions/inactions might subject them to FCA liability.

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[4] *United States v. Triple Canopy, Inc.*, 775 F.3d 629, 637 (4th Cir. 2015).

II. Implied certification is not a viable theory of FCA liability because the Act was not intended to have such a broad scope, and should not be expanded. First, the theory of implied certification in FCA cases renders part of the statute superfluous. Second, although the implied certification theory does not eliminate the "knowing" element of an FCA claim, in reality the broad reach of an FCA claim for implied certification would render the knowing element irrelevant, and thus remove the protection the knowing element provides to defendants from meritless suits. Lastly, construing the FCA to include claims for implied certification would be contrary to public policy, given the remedies available to the Government for regulatory and contractual violations. Accordingly, the FCA should not be expanded beyond its intended scope to include liability for claims of implied certification.

ARGUMENT

I. The Implied Certification Theory Is Not Viable Because It Is Not Amenable to an Objective Test

Although several circuit courts have applied some form of implied certification to find liability under the FCA, CareSource urges this Court to find that the implied certification theory of legal falsity is not viable given the uncertainty such liability would create and the far-reaching effects of such uncertainty on putative defendants, particularly illustrative in the impact on the nonprofit healthcare industry.

Implied certification claims cannot neatly fit into a single objective standard that would meet the needs and realities of all who contract with the Government,

across all affected industries. The key provision of the FCA at issue imposes civil liability on any person who knowingly submits a "false or fraudulent claim for payment or approval" to the Government. 31 U.S.C. § 3729(a)(1)(A) (2012).

This provision has long covered "factually false claims," or those which contain "an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided." *Mikes v. Straus*, 274 F.3d 687, 697 (2d Cir. 2001). Section 3729(a)(1) has also been applied to cover "legally false claims" containing an express certification of compliance with the terms of a contract, statute, or regulation. *United States ex rel. Wilkins v. United Health Group*, 659 F.3d 295, 305 (3d Cir. 2011). Factually false claims and legally false claims with express certifications of compliance are not open to interpretation.

Conversely, to extend liability under § 3729(a)(1) to find that all claims for payment or reimbursement necessarily imply certification of compliance, without identifying any particular contractual provision, statute, or regulation, does not allow a ready, objective determination of whether such a claim is false or fraudulent, or not. For example, even if a hospital's claim for payment contains no express certification of compliance and such claim is factually true—all services were provided and are eligible for Medicare reimbursement—the hospital's claim could be deemed false by the hospital's failure to be in substantial compliance with any number of statutes or regulations, even if they are ancillary to the services for which reimbursement is requested. The addition of

conditions and limitations to liability does not resolve the concern of lack of notice to putative defendants as to what actions or inactions may be subject to FCA liability.

A. Adding Conditions and Limitations to Liability Does Not Remove the Ambiguity Implied Certification Theory Creates

Trying to limit implied certification liability is no better than putting a bandage on a six-inch wound—it may temporarily work but it cannot be a permanent solution. The difficulty in trying to craft a standard for implied certification liability is perhaps best illustrated by issues arising from the healthcare industry. In *Mikes v. Straus*, the Second Circuit acknowledged why the implied certification theory is troublesome:

> [C]aution should be exercised not to read this theory expansively and out of context. The *Ab-Tech* rationale, for example, does not fit comfortably into the health care context because the False Claims Act was not designed for use as a blunt instrument to enforce compliance with all medical regulations . . . .

274 F.3d 687, 699 (2d. Cir. 2011).

In *Mikes*, the Second Circuit explains that within a section of the Medicare statute there can be further divisions of conditions of participation: provisions governing medical necessity of a procedure and its quality. *Id.* A relator, as was the case in *Mikes*, could advance the argument that failing to meet a certain quality of care standard is a false certification of compliance that should be subject to FCA liability. *Id.* The Second Circuit recognized that "permitting *qui tam*

plaintiffs to assert that defendants' quality of care failed to meet medical standards would promote federalization of medical malpractice" and "that the courts are not the best forum to resolve medical issues concerning levels of care." *Id.* at 700.

Although the Second Circuit concluded it was still possible for the implied certification theory to be viable, its emphasis on the poor fit of this theory to the healthcare industry should not be ignored. A comparison between what may occur when a provider violates a Medicare regulation with what may occur if that violation is subject to FCA liability illustrates the magnitude with which the implied certification theory amplifies liability to healthcare providers.

Conditions of participation can address issues such as medical staff, nursing services, laboratory services, discharge planning and infection control. *See, e.g.*, 42 C.F.R. §§ 482.21 to 482.66 (2012) (setting out Medicare conditions of participation for hospitals). If these conditions are not met, the relevant Medicare regulations make clear that the provider is not excluded from the program, and payment is not stopped, unless the Centers for Medicare and Medicaid Services (CMS) determine an immediate threat to the health or safety of patients exists. *Id.* at § 482.28.[5] Noncompliant providers are given a reasonable amount of time to achieve compliance, and are even given the right to appeal their termination, while continuing to provide services. *Id.* at §§ 489.53-54. Thus, even when

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[5] *See also*, Robert Fabrikant and Glenn E. Solomon, *Application of the Federal False Claims Act to Regulatory Compliance Issues in the Health Care Industry*, 51 ALA. L. REV. 105, 123 (1999).

a hospital may not be in substantial compliance with a Medicare regulation, CMS will not necessarily exclude the hospital from the program or stop payment. The hospital or provider is given an opportunity to remedy the violation and still receive reimbursement for Medicare eligible services.

By contrast, if FCA liability is permitted under the implied certification theory, and a hospital that submitted a request for payment was found to be noncompliant with some Medicare regulation or statute, that hospital would be subject to a civil penalty of not less than $5,500 and not more than $11,000, *per* claim, plus 3 times the amount of damages under the FCA. 31 U.S.C. § 3729(a)(1) (2012); 28 C.F.R. § 85.3(a)(9) (2015). While the regulatory enforcement process allows the hospital to become compliant, and still participate in the program and receive payment from the Government, FCA liability under the implied certification theory would impose mandatory treble damages. Thus, the effect of noncompliance is significantly greater under FCA implied certification than under existing regulatory remedies.

The healthcare industry is heavily regulated, making it extremely challenging for all providers and suppliers to know and understand every law and regulation that governs their respective operations.[6] Even if all providers and suppliers know and understand all laws and regulations which govern their operations, it is not reasonable to expect that an entity knows whether it is in full compliance, at all times,

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[6] Fabrikant, *supra* note 5, at 151.

with each and every one of those laws and regulations.[7] This leads to another flaw in imposing liability under the implied certification theory—"it seeks to impose liability upon the purported expression of a legal opinion or conclusion, not an objectively verifiable statement of fact."[8] For example, a healthcare provider may be of the opinion that it is in full compliance with every Medicaid statute and regulation to which it is subject, but in the event this is not factually true, such an opinion should not serve as the basis for a FCA claim. If the provider has a reasonable, good faith belief that it has complied with its obligations under the law, it would be unjust to hold that the provider has impliedly made a knowingly false statement or certification that subjects it to FCA liability.[9]

Short of requiring an express certification of compliance in a payment request, there will always be room for ambiguity between participation and payment, and whether a defendant's reasonable opinion of compliance equates to a false statement of fact. As such, application of the theory of implied certification raises more questions and problems than it solves.

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[7] *Id.*

[8] *Id.* at 153, *citing West v. Western Casualty & Surety Co.*, 846 F.2d 387, 393 (7th Cir. 1988) (indicating that a statement that expresses an opinion is not actionable as a misrepresentation).

[9] *See* John T. Boese, *et al.*, *Why Thompson is Wrong: Misuse of the False Claims Act to Enforce the Anti-Kickback Act*, 51 ALA. L. REV. 1, 29 (1999) (explaining that the preparation of Cost Reports requires interpretation of government policies and is subject to good faith differences of opinion).

B. Strict Adherence to the Other Elements of an FCA Claim Do Not Remedy the Lack of an Objective Test for Liability under the Implied Certification Theory

Adherence to the other elements of an FCA claim do nothing to assist the creation of an objective standard. To the contrary, an examination of whether an implied certification was false, material to the Government's decision to pay, and knowingly made necessarily requires a fact-intensive review. Accordingly, the argument that abuse of the implied certification theory will be curtailed by strict enforcement of the Act's scienter and materiality requirements is feeble, at best. *But see United States v. Triple Canopy*, 775 F.3d 628, 637 (4th Cir. 2015); *United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 378 (1st Cir. 2011).

1. Scienter can be abused to render its protection meaningless

Under the FCA's scienter requirement, it is sufficient to show that a defendant knew or recklessly disregarded a risk that its implied certification of compliance was false. *See Shaw v. AAA Eng'g & Drafting, Inc.*, 213 F.3d 519, 530 (10th Cir. 2000). At least one court has found liability under this standard when the defendant was merely "familiar" with underlying Medicare regulations, the violation of which was alleged to give rise to FCA liability. *See, e.g., United States ex rel. Augustine v. Century Health Servs.*, 289 F.3d 409, 416 (6th Cir. 2002) (finding liability under the FCA when defendants testified they were aware of Medicare regulations governing reimbursement).

Moreover, because of the low threshold for stating a claim for "reckless disregard," the scienter requirement does not offer any meaningful protection against abusive lawsuits, particularly, *qui tam* suits.[10] Because of the doctrine of imputed knowledge, liability under the FCA can be found if even one employee knew or recklessly disregarded the falsity of an implied certification submitted by its employer. *United States ex rel. Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908, 918 n.9 (4th Cir. 2003). Similarly, courts have attempted to use collective corporate knowledge theory—where the knowledge of a corporation is the sum knowledge of all of its employees—to impose FCA liability under the implied certification theory. *See Miller v. Holzmann*, 563 F.Supp.2d 54, 100 (D.D.C. 2008), *aff'd in part and vacated in part on other grounds*.

Although the Fourth Circuit held that knowledge of one employee was sufficient to establish FCA liability, it recognized the danger of the collective knowledge theory, stating that all a plaintiff would need to do to meet the scienter requirement would be to "piec[e] together scraps of 'innocent' knowledge held by various corporate officials, even if those officials never had contact with each other or knew what others were doing in connection with a claim seeking government funds." *Harrison*, 352 F.3d at 918 n.9. Indeed, this is

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[10] Richard Doan, *The False Claims Act and the Eroding Scienter in Healthcare Fraud Litigation*, 20 ANNALS HEALTH L. 49, 67-69 (2011) (discussing the inconsistency in application of the standard for reckless disregard and discussing that in practice the application is little more than gross negligence, which should not be sufficient under the FCA to impose liability).

precisely what a plaintiff could do to impose liability for noncompliance with a statute or regulation that may be ancillary to the actual claim for payment.

Additionally, strict adherence to the scienter requirement will not permit an implied certification theory case to be resolved on a dispositive motion because it raises a question of fact. *See United States ex rel. Taylor-Vick v. Smith*, 513 F.3d 228, 231 (5th Cir. 2008) (noting that when a case requires the court to make a determination about a party's state of mind, summary judgment may not be appropriate). Thus, the scienter requirement will not eliminate plaintiffs' abuse of the FCA or the substantial discovery and litigation costs a defendant must endure.

2. The materiality requirement can be distorted to create liability without sufficient regard to the actual falsity or fraudulent nature of the implied statement or certification

Relying upon materiality in order to determine falsity conflates these two elements of FCA liability, and subjects defendants to abusive litigation. By analyzing the prerequisite to payment as either part of a materiality analysis, a falsity analysis, or both, liability may improperly or inconsistently be found under the implied certification theory where it is not warranted.

Under the FCA, the definition of "material" is "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4) (2012). This definition of materiality is one of the ways in which the Fraud Enforcement and Recovery Act of 2009 (FERA)

amended the FCA. As revised, the materiality element creates a relatively low threshold for the Government.[11]

For example, the First Circuit determined that even insignificant contract provisions or regulations could be "capable of influencing" the Government's decision to pay. *United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 394 (1st Cir. 2011) ("We cannot say that, as a matter of law, the alleged misrepresentations in the hospital and physician claims were not capable of influencing Medicare's decision to pay the claims.").

The danger of such a rule is magnified when considered in the context of a *qui tam* action. Applying the analysis of *Blackstone*, a relator could bring an action against a defendant for failing to disclose a knowing violation that was capable of influencing the Government's decision to pay, *even if* the Government had exercised its discretion not to pursue such violations in the past, would have pursued an administrative remedy, and would not have chosen to

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[11] John T. Boese, Use of the False Claims Act to Enforce Federal Regulations: Necessary Limits on False Certification Cases Brought Under the Civil False Claims Act, *What You Don't Know Could Hurt You: An Examination of the Expanding Federal False Claims Act and its Impact on Regulated Businesses*, Panel Discussion at the Environmental, Mass Torts & Products Liability Litigation Committees' Joint CLE Seminar (Jan. 29-31, 2015), *available at* http://www.americanbar.org/content/dam/aba/administrative/litigation/materials/2015-joint-cle/written_materials/02_what_you_don't_know_could_hurt_you_an_examination.authcheckdam.pdf

intervene in the relator's case.[12] The result: a defendant that might otherwise have been subject to contract damages or a penalty under a regulatory/administrative enforcement scheme is now subject to treble damages for something the Government likely deemed unworthy of severe punishment.

Likewise, the Ninth Circuit's materiality analysis obscures the difference between violations of conditions of participation and conditions of payment. In *United States ex rel. Hendow v. University of Phoenix*, the Ninth Circuit dismissed the distinction between a condition of participation and a condition of payment stating that it was "a distinction without a difference." 461 F.3d 1166, 1176-77 (9th Cir. 2006). The Ninth Circuit instead focused on whether the University's failure to comply with a restriction on enrollment incentive compensation was material to the Government's decision to pay. *Id.*

Thus, even assuming that some limiting conditions were imposed for determining falsity for implied certification claims, *Hendow*'s approach demonstrates the inherent lack of uniformity in application and the conflation with materiality. *Hendow* determined that conditions of participation and payment were one and the same—which is in direct conflict with the conclusion the Seventh Circuit reached regarding the very same law, 20 U.S.C. § 1094(a), in *United States v. Sanford-Brown, Ltd.*, 788 F.3d 696 (7th Cir. 2015).

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[12] Christopher L. Martin, Jr., *Reining in Lincoln's Law: A Call to Limit the Implied Certification Theory of Liability Under the False Claims Act*, 101 CAL. L. REV. 227, 259-261 (2013).

Additionally, after deciding that there was no difference between conditions of payment and conditions of participation for purposes of the Higher Education Act, the court in *Hendow* concluded that implied certification could be a predicate for FCA liability as long as it was "relevant to the government's decision to confer a benefit." *Hendow*, 463 F.3d at 1173. If a relevancy determination in this context is akin to relevancy under the Federal Rules of Civil Procedure, the implication for liability would be limitless.[13]

Moreover, in *Hendow* the Ninth Circuit sought to distinguish its analysis from that of the Second Circuit in *Mikes* by arguing that because the reasoning in *Mikes* was confined to the Medicare context the dichotomy between conditions of payment and participation was limited to Medicare cases. *Id.* This justification is troubling because if the implied certification theory is recognized as a viable theory to impose FCA liability, its application should be based upon a uniform, objective standard applicable to all industries. The suggestion that different conditions or limitations should be applied to different industries—be it healthcare, higher education, or defense contracts—only furthers the point that the implied certification theory is not viable.

The Fifth Circuit's reasoning further underscores that adherence to materiality will not eliminate the abusive use of implied certification theory. *United*

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[13] *See, e.g, Oppenheimer Fund v. Sanders*, 437 U.S. 340, 351 (1978) (explaining the broad scope of the term "relevancy" under the Federal Rules of Civil Procedure).

States ex rel. Steury v. Cardinal Health, Inc. ("*Steury I*"), 625 F.3d 262 (5th Cir. 2010). In *Steury I*, the Fifth Circuit concluded that a defendant would not be liable under the FCA for false certification of compliance with a regulatory requirement, even if that certification was "material" to the Government's decision to pay, if payment was not conditioned on compliance with the statute, regulation, or contract provision. 625 F.3d at 269.[14] Under the Fifth Circuit's analysis, "[t]he prerequisite [to payment] requirement has to do with more than just the materiality of a false certification; it ultimately has to do with whether it is fair to find a false certification or false claim for payment in the first place." *Id.*

Thus, courts differ on whether prerequisite of payment or condition of payment is part of a materiality analysis or a question of falsity. The differing application and analysis of materiality demonstrates that implied certification claims do not fit into an objective test, and, therefore, are susceptible to inconsistency in application. This inconsistency in application will result in over-inclusiveness. Defendants that are not intentional bad actors, and whose actions cannot be deterred because they did not submit a claim knowing the claim would be deemed false, are subject to extreme and disproportionate punishment. The noncompliance and violations that have become the basis for implied certification claims are more proportionately addressed by regulatory enforcement and should not be a basis for FCA liability

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[14] John T. Boese, *Civil False Claims and Qui Tam Actions* § 2.03[G], at 2-213 (4th ed. 2011).

under the judicial construct of implied certification of compliance.

3. Materiality analysis hinders early resolution of implied certification claims

Relying upon a materiality analysis to bolster the viability of implied certification claims will also negatively impact the judicial process for such FCA claims. If courts become bogged down in a materiality analysis before they can determine whether a claim for relief has been stated under the implied certification theory, implied certification cases will not be capable of resolution on a motion to dismiss. Determining whether the Government's decision to pay a claim is conditioned upon compliance with a statute or regulation is a fact-intensive question. *See United States ex rel. Thompson v. Columbia / HCA Healthcare Corp.*, 125 F.3d 899, 902-03 (5th Cir. 1997) (denying a motion to dismiss because the court was unable to determine from the record whether payment was conditioned on defendants' certifications of compliance, therefore remanding for further factual development).

Indeed, such a question would almost certainly preclude granting a motion to dismiss because it is a factual question regarding what a government agency considers in deciding whether to approve a claim for payment. If the *Hendow* definition of materiality were to prevail, an implied certification claim would be actionable under the FCA, and capable of surviving a motion to dismiss, provided a plaintiff alleged sufficient facts to argue that the implied certification was "relevant" to the Government's decision to pay. Not only would such a definition of materiality create a very low threshold for plaintiffs to meet, but it would

also obliterate any chance for the creation of a uniform, objective test for implied certification claims.

This concern about the ability to adjudicate a motion to dismiss is a practical concern, particularly in the healthcare industry.[15] Due to the treble damages and mandatory per-claim penalties defendants face under 31 U.S.C. § 3729(a), defendants are typically forced to settle if a motion to dismiss fails[16]—often for reasons that have nothing to do with the strength of the plaintiff's case, such as the financial costs and other burdens of continuing to litigate the case through discovery, and the defendant's rational concern that the punitive liability available under the FCA can transform even meritless claims into "bet the company" litigation.[17] Thus, defendants may feel forced into settling even if the merits of a case are questionable given the inherent inability to have the case dismissed, because of the lack of an objective test for implied certification claims.

When all of these factors are taken into consideration, it is clear that the theory of implied certification is not viable—it is not amenable to an objective test and attempts to limit or condition liability on certain factors do not resolve the problems of inconsistency, lack of notice, or subjective

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[15] *See* Dennis Oscar Vann Jr., *Stemming the Federal Tort Fountain: Why Federal Courts Should Maintain Implied Certification Limitations on Qui Tam Suits Against Nonclaimant Defendants*, 47 GA. L. REV. 999, 1027 (2013).

[16] *Id.*

[17] *Id.*

determinations. In addition to not being capable of a fair, uniform, objective determination, implied certification theory also finds no support in the text of the statute. For these reasons, implied certification theory should not be permitted as a basis for FCA liability.

II. The Scope of the FCA Was Never Intended to Reach Implied Certifications of Compliance with Every Potentially Applicable Law, Regulation, and Policy

A. The Rules of Statutory Interpretation Do Not Support Finding Implied Certification Theory of Liability under the FCA

1. Permitting a claim for implied certification renders § 3729(a)(1)(B) superfluous

The implied certification theory is not viable within the FCA framework because its application renders § 3729(a)(1)(B) superfluous or meaningless. The rules of statutory construction require courts to give meaning to every word in a statute. *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973). Indeed, this Court has stated: [C]ourts must presume that a legislature says in a statute what it means and means in a statute what it says there." *Connecticut Nat'l Bank v. Germain*, 503 U.S. 249, 253-54 (1992) (citations omitted). This Court has also stated that "[a] statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant." *Codry v. United States*, 556 U.S. 303, 314 (2009). Likewise, where courts analyze congressional intent, a canon of construction should not be followed when such

application "would be tantamount to a formalistic disregard of congressional intent." *Rice v. Rehner*, 463 U.S. 713, 732 (1983). That Congress did not intend for implied false certifications to be a valid theory of FCA liability can be found in a close reading of the statute itself. This Court should therefore reject the theory of implied certification because to accept it as a valid theory of liability under the FCA would render superfluous an entire provision of the FCA.

The implied certification theory has two primary forms: (1) that the defendant's submission of a claim impliedly certified compliance with some obligation or set of obligations; and (2) that a defendant's prior express certification of compliance with an obligation implied certification that the defendant would maintain compliance with such obligation in the future.[18] It is important to recognize these two discrete forms of "implied certification" in order to understand how the statutory language would apply in each situation.

Pre-FERA, the FCA included two provisions relevant to the implied certification argument. Under § 3729(a)(1) of the FCA, those who "knowingly present[], or cause[] to be presented" to the United States "a false or fraudulent claim for payment or approval" are liable. Additionally, § 3729(a)(2) imposes liability on individuals who "knowingly make[], use[], or cause[] to be made or used, a false record to get a false or fraudulent claim paid or approved by the

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[18] *See* Marcia G. Madsen, *False Claims Act: What Government Contractors Should Know About the Implied Certification Theory of Liability*, 939 PLI/COMM. 471, 475 (2011).

Government." The FERA amendments to the FCA in 2009 modified the language of § 3729(a)(1), removing the requirement of presentment to the United States and redesignating the section as § 3729(a)(1)(A). The FERA amendments also renumbered former § 3729(a)(2) as § 3729(a)(1)(B) and revised the subsection to impose liability on those who "make[], use[] or cause[] to be made or used, a false record or statement material to a false or fraudulent claim."

The post-FERA § 3729(a)(1)(B) of the FCA requires that a false statement or record be material to the false or fraudulent claim, while § 3729(a)(1)(A) includes no materiality requirement. Both the pre- and post-FERA versions of the FCA require a defendant to have acted "knowingly."

Courts have typically applied § 3729(a)(1)(A) to implied certification cases not involving a prior express certification because § 3729(a)(1)(B) specifically references a "false record or statement" while § 3729(a)(1)(A) does not. *See, e.g., United States ex rel. Wilkins v. United Health Grp.*, 659 F.3d 295, 306-07 (3d Cir. 2011), *citing Shaw v. AAA Eng'g & Drafting, Inc.*, 213 F.3d 519, 531 (10th Cir. 2000). This omission of a reference to a "false record or statement" in § 3729(a)(1)(A) is what has led some courts to conclude that an expressly false statement or record is not required under § 3729(a)(1)(A). Accordingly, the implied certification cases, in which no express statement was ever made, would have to be brought under § 3729(a)(1)(A), if they can be brought at all.

Analysis of claims where the implied certification theory rests on the premise that a defendant's ***prior*** express certification of compliance implies certification

of future compliance exemplifies the conflict between the implied certification theory and the text of the Act. Under this argument, the prior express certification ***might be*** the "false record or statement" required by § 3729(a)(1)(B). But, a prior express certification that falsely implies certification of future compliance ***might also be*** an inherently false or fraudulent claim that should instead be analyzed under § 3729(a)(1)(A). In that case, there would be overlap between what is included within the scope of § 3729(a)(1)(A) and what is included within the scope of § 3729(a)(1)(B).

This potential overlap in statutory interpretation underscores that the FCA was never meant to reach cases of false implied certification in the first place since, if § 3729(a)(1)(A) is broad enough to reach implied false certifications based solely on the fact that the defendant submitted a claim, it certainly is broad enough to reach the implied false certifications stemming from a defendant's prior express certification of compliance, thereby rendering § 3729(a)(1)(B) superfluous.[19] From this premise, the logical conclusion is that Congress actually did not intend to include implied false certifications within the scope of the FCA at all because courts presume that Congress did not intend to include surplusage in a statute. Accordingly, implied certification theory is not a permissible basis for FCA liability.

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[19] Pari I. McGarraugh, Implied Certification under the False Claims Act: Crafting Appropriate Limits (2012) (unpublished term paper, University of Minnesota) (available at https://www.mnbar.org/docs/default-source/sections/implied-certification-under-the-false-claims-act-crafting-appropriate-limits.pdf?sfvrsn=4).

2. Intent of the FCA: erosion of the "knowing" concept and restitution vs. deterrence

Another manner in which the implied certification theory is inconsistent with congressional intent is apparent in the erosion of the "knowing" element of the FCA. The "knowing" element exists to thwart intentional or reckless bad actors, not actors that are merely negligent or make innocent mistakes. In this way, the Act seeks to deter future bad acts. The Act cannot deter those who are ignorant of their misdeeds. In practice, the implied certification theory eliminates the protection the "knowing" element provides, and therefore does nothing to further the aim of deterrence, but serves only to punish.

(a) Implied certification erodes the protection the "knowing" requirement is intended to provide

Theoretically, implied certification claims cannot ensnare innocent or negligent acts of noncompliance because the FCA only imposes liability for knowingly submitting a false claim. In practice, however, the nature of an implied certification claim has the effect of making the "knowing" element irrelevant—in direct contradiction to the stated text of the Act.

"Knowing" and "knowingly" are defined to include actual knowledge of the information, "deliberate ignorance of the truth or falsity of the information," or reckless indifference to it. § 3729(b)(1)(A). The plaintiff's burden to establish the "knowing" element is to prove the defendant knew the information provided was false; it is not necessary that the plaintiff prove the

defendant intended to defraud the Government.[20] Although it is not necessary that the plaintiff prove intent to defraud, the FCA is, at heart, a statute targeting fraud on the Government. *United States ex rel. Owens v. First Kuwaiti Gen. Trading & Contracting Co.*, 612 F.3d 724, 728 (4th Cir. 2010). Indeed, courts recognize that not every breach of a government contract is subject to FCA liability and not every violation of a statute or regulation is necessarily a false or fraudulent claim under the FCA. *See Steury*, 625 F.3d 262, 268 (5th Cir. 2010) (on contracts); *United States ex rel. Thompson v. Columbia / HCA Healthcare Corp.*, 125 F.3d 899, 902 (5th Cir. 1997) (on statutes and regulations).

The FCA does not, however, statutorily define the term "false." *See Mikes v. Straus*, 274 F.3d 687, 696 (2d Cir. 2001); *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 785 (4th Cir. 1999) ("Taking the phrase 'false or fraudulent claim' in its entirety, though, is more complicated, because the phrase has become a term of art."). In *Mikes*, the Second Circuit reasoned that "[t]he juxtaposition of the word 'false'

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[20] Gregory Klass and Michael Holt, *Implied Certification under the False Claims Act*, 41 PUB. CONT. L. J. 1, 7 fn. 50 (2011) ("As a civil remedy designed to make the Government whole for fraud losses, the civil False Claims Act currently provides that the Government need only prove that the defendant knowingly submitted a false claim. However this standard has been construed by some courts to require that the Government prove the defendant had actual knowledge of fraud, and even to establish that the defendant had specific intent to submit the false claim . The [Senate Judiciary] Committee believes this standard is inappropriate in a civil remedy and presently prohibits the filing of many civil actions to recover taxpayer funds lost to fraud.").

with the word 'fraudulent,' plus the meaning of the words comprising the phrase 'false claim,' suggest an improper claim is aimed at extracting money the government otherwise would not have paid." 274 F.3d at 696.

Applying this definition to an implied false certification, however, is vexing. For example, when a hospital submits a claim to Medicare for reimbursement, proponents of the theory of implied false certifications would argue that the hospital is impliedly certifying that it is in compliance with all applicable Medicare statutes and regulations. Some of those regulations or statutes may affect the hospital's ability to be reimbursed for the claim submitted, but those regulations or statutes may: (1) not allow the Government to withhold payment; (2) permit the Government to exercise discretion in whether to make the payment; or (3) create some other remedial process for violation but still allow for payment.[21] Under such circumstances, whether the hospital knowingly submitted a false claim such that it could be subject to FCA liability is open to interpretation and cannot be determined at the time the claim for reimbursement was made. The hospital may have acted "with reckless indifference" to the status of its compliance with all regulations and statutes and submitted a claim for payment. But, if it is unknown or undeterminable whether the claim's failure to comply in every respect

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[21] Klass, *supra* note 20, at 24, 49-50 (discussing the issues with the compliance-condition rule set forth in *Mikes v. Straus* 274 F.3d 687 (2d Cir. 2001) by questioning if compliance is conditional if the Government might have paid the claim, or if the Government had a duty to pay the claim even if it knew of the violation).

with the regulation or statute rendered it false—given that the Government may or may not have the ability to withhold payment or choose to withhold payment depending on the severity of the violation, impact on the Government, and alternatives remedies, the protection of the "knowing" element against abusive claims is lost. The requirement of knowingly submitting a "false" statement is obscured, because the action may be "knowing" but not necessarily "knowingly false".

Accordingly, the implied certification theory will almost certainly ensnare cases where a defendant has submitted a claim for payment while "knowingly," as the term is defined, in violation of some contractual provision, statute, or regulation, ***but yet*** without knowing or without certainty that such violation would necessarily cause the Government not to pay the claim. Indeed, if the Government could exercise its discretion in approving a request for payment, even if the Government was aware of the noncompliance, defendants would have no notice of when noncompliance may subject them to FCA liability under the implied certification theory and when they would simply be subject to applicable regulatory enforcement measures. Thus, the "knowing" element would not offer any protection to defendants from the initiation of abusive *qui tam* suits.

(b) The overbreadth of implied certification claims supports neither restitution nor deterrence

While the overarching purpose of the FCA is, and has been, to combat fraud, there is a debate over

whether this purpose should be achieved through restitution or deterrence and punishment.[22]

Arguments in favor of expanding FCA liability to include implied certification claims suggest that such expansion fits with congressional intent because it conforms the FCA to common-law—creating liability not only for affirmative statements, but also for omissions.[23]

One problem with creating liability for a defendant's failure to inform the Government that it is not in perfect or substantial compliance with each and every regulation, statute, or contractual provision to which it may be subject is the reality of what such a duty might entail and the insignificant impact it would have where the "primary purpose of the FCA 'is to indemnify the government . . . against losses caused by a defendant's fraud.'" *United States ex rel. Wilkins v. United Health Grp.*, 659 F.3d 295, 305 (3d Cir. 2011) *quoting Mikes v. Straus*, 274 F.3d 687, 696 (2d Cir. 2001).

Indeed, allowing claims to be brought under the implied certification theory swings the hypothetical pendulum far from restitution toward punishment. Given the erosion of the "knowing" requirement, the goal of punishment is inconsistent because it is not possible to deter a defendant from an action or inaction that it does not have fair notice will subject it to such severe liability.

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[22] Doan, *supra* note 10, at 64.

[23] Martin, *supra* note 12, at 232-33.

Indeed, because the knowledge of one employee has been held sufficient to meet the scienter requirement, large entities like hospitals or health plans could be faced with catastrophic consequences for the reckless disregard of one person, for failing to maintain compliance with one of a multitude of Medicaid or Medicare statutes or regulations—despite the Government receiving what it contracted for, at the price it agreed to pay. Not only is such an outcome inconsistent with restitution, it is certainly not capable of deterrence, acting only as a punishment for an entity who, for all intents and purposes, may not have been aware of the noncompliance and was not given a fair opportunity to remedy the issue short of FCA treble damages.

Additionally, for implied certification claims, the nondisclosure at issue does not necessarily have to directly correlate to how many times an entity billed the Government for goods or services rendered. For example, while a plaintiff could allege that a defendant was out of compliance with a single contractual or regulatory requirement for a period of several months, if the theory of implied certification is accepted, every claim submitted during that timeframe would be subject to the multiplying effect of the per-claim fine structure of the FCA—which could have disastrous consequences for the entity and would be completely out of proportion to the severity of the alleged contractual or regulatory compliance issue.[24]

These scenarios are likely to occur with regularity under the implied certification theory, but are not

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[24] Klass, *supra* note 20, at 54.

consistent with the intended scope of the FCA. Accordingly, the implied certification theory has no place as a theory of liability under the FCA.

B. Expansion of the FCA Beyond the Bounds Congress Intended Would be Contrary to Public Policy

In addition to not fitting within the statutory scheme that Congress has enacted, implied certification theory is not viable because it contravenes other remedies, including the very remedial process that the Government has established to address noncompliance with statutes and regulations. *United States ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694, 702 (4th Cir.), *cert denied*, 135 S. Ct. 85 (2014).

The idea of conditioning payment on compliance under the implied certification theory "undermine[s] the government's own administrative scheme for ensuring that [entities] remain[] in compliance and for bringing them back into compliance when they fall short of what the Medicare [and Medicaid] regulations and statutes require." *United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1220 (10th Cir. 2008). Furthermore, permitting FCA liability for noncompliance, particularly because of the availability of *qui tam* suits, might prevent the Government from proceeding through the remedial process, through which the Government might choose to waive administrative remedies or impose a less drastic sanction. *See id.* The implied certification theory, therefore, would in effect allow *qui tam*

plaintiffs to obliterate regulatory discretion granted to government agencies.[25]

This is particularly true in the healthcare context, where healthcare organizations participating in federal healthcare programs are subject to several layers of oversight and a variety of remedial actions for noncompliance. The Social Security Act contains 23 grounds for healthcare organizations to be excluded from participating in federal healthcare programs and gives the Department of Health and Human Services (HHS) Office of Inspector General the authority to impose such exclusions.[26] Healthcare organizations are given the opportunity to respond to proposed exclusions, and they have the right to appeal exclusions to administrative law judges, the HHS Departmental Appeals Board, and federal court.[27] In practice, HHS often resolves the possibility of exclusion through the use of corporate integrity agreements that allow

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[25] Klass, *supra* note 20, at 43 (stating that when the Government brings an FCA suit it has likely balanced any costs of interference with regulatory mechanisms with benefits of the Act).

[26] Office of Inspector General, U.S. Department of Health & Human Services, Exclusion Authorities, http://oig.hhs.gov/exclusions/authorities.asp (last visited Jan. 14, 2016) (the OIG imposes exclusions under the authorities of sections 1128 and 1156 of the Social Security Act).

[27] 42 C.F.R. §§ 1001.2001-2007 (2015) (setting forth the administrative notice and appeals process).

providers to continue participating under increased oversight and monitoring.[28]

In addition, Medicare participating providers are subject to an overpayment recovery process that includes five levels of appeal.[29] Potential overpayments are identified by a variety of HHS contractors, including Medicare Administrative Contractors, Zone Program Integrity Contractors, and Recovery Audit Contractors. Once an overpayment has been identified, the provider may request redetermination with the contractor, reconsideration by a Qualified Independent Contractor, a hearing before an administrative law judge, a review by the Medicare Appeals Council, and judicial review in a United States District Court.[30] Healthcare organizations are also subject to state licensing authorities and regulators and the possibility of malpractice suits. These measured remedies stand in sharp contrast to the "blunt instrument" of the FCA.

Additionally, the Government would not be without recourse in dealing with noncompliant defendants if FCA liability cannot be imposed for implied certifications of compliance. The Government has other remedies to recover funds wrongfully or illegally paid, which would make the Government whole and be sufficiently deterrent, without imposing the steep

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[28] Publication of the OIG Compliance Program Guidance for Hospitals, 63 Fed. Reg 8989 (February 23, 1998).

[29] 42 U.S.C. § 1395ff (2012).

[30] *Id.*

penalty of treble damages.[31] For example, the Government can recover funds through the doctrine of "payment by mistake." This doctrine is similar to the FCA in that it allows the Government to recover funds from parties who received payment directly and from third parties that "participated in and benefited from the tainted transaction" and that the critical element is whether the erroneous belief was material to the decision to pay. *United States v. Mead*, 426 F.2d 118, 124 (9th Cir. 1970); *LTV Educ. Sys., Inc. v. Bell*, 862 F.2d 1168, 1175 (5th Cir. 1989).

In *United States ex rel. Roberts v. Aging Care Home Health, Inc.*, the Louisiana District Court relied upon the payment by mistake doctrine where the defendants' certifications of statutory compliance were false, and, therefore, material to the Government's decision to pay. 474 F. Supp. 2d 810, 819 (W.D. La. 2007). Because the payment by mistake doctrine is equitable, punitive damages cannot be assessed.[32] The Government receives restitution, and the defendant is not out-of-pocket the significant amount an FCA award of damages would impose.

The monetary comparison is instructive. The court in *Aging Care* made the following calculations: under the FCA, because of the mandatory imposition of treble damages, the defendant would have been fined $4,665,011.64 whereas under the theories of unjust

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[31] Doan, *supra* note 10, at 71-74 (2011) (discussing various alternative remedies available to Government to address health care fraud and abuse that is not covered by the FCA).

[32] Doan, *supra* note 10, at 73.

enrichment or payment by mistake the defendant would have to reimburse the Government only $427,503.88. *United States ex rel. Roberts v. Aging Care Home Health Inc., (Aging Care II)*, No. 02-2199, 2008 WL 2945946, at *11 (WD. La. Jul. 25, 2008). Similarly, in *United States v. Rogan*, the court determined that under the FCA the defendant would have been required to pay $64,259,032.50, but under the payment by mistake doctrine, the Government was owed only $16,864,677.50, plus interest. 459 F.Supp.2d 692, 727-28 (N.D. Ill. 2006).

The extreme disparity between FCA damages and restitution damages illustrates why alternative remedies are more appropriate and use of the FCA would be against public policy. When the violation at issue is one not directly related to the falsity or fraudulent nature of the goods and services provided under the contract, but some ancillary statutory, regulatory, or contractual violation, not only would the FCA not deter action, but also, the Government may not have been deprived of funds from the treasury. In those situations, the remedies under the FCA are not appropriate.

Implied certification theory acutely affects nonprofit healthcare providers. Nonprofit healthcare providers serve millions of citizens, and seek to provide the highest level of care at an affordable cost. These providers are required to make an express certification with requests for payment, and, therefore, are already subject to FCA liability if they knowingly and expressly certify compliance when in fact they are not compliant. Where certification of compliance with some statute or regulation is not included among what these providers

must certify, such implied certification should not be a basis for FCA liability. Having to divert resources to defend against implied certification claims, of which providers may have no notice that such action would subject them to FCA liability, would jeopardize their mission and ability to serve their members—an indigent population that depends on such nonprofits to maintain their health and well-being.

Rather than subjecting healthcare providers to the harsh and steeper damages mandated by the FCA, the agencies charged with ensuring compliance and enforcement of statutory and regulatory violations should have primary responsibility for determining the consequences of implied false certification of compliance, not the courts.[33] Implied certification theory does not accomplish the goal of deterring bad actors, but instead subjects defendants to treble damages for actions that they may not know are subject to FCA liability. Adhering to agency enforcement rather than implied certification theory eliminates the lack of notice of culpable conduct, the lack of uniformity in applicable penalties, the over-inclusivity of liability, and the abusive use of *qui tam* suits. The implied certification theory is a judicial construct not found in or supported by the Act, and should not be permitted as a basis of FCA liability.

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[33] Fabrikant, *supra* note 5, at 131 (Discussing that CMS has primary responsibility for qualifying healthcare facilities for certification and that "courts considering FCA claims based on alleged failure to satisfy the requirements for certification should defer the issue to [CMS] based on the doctrine of primary jurisdiction.").

CONCLUSION

The judgment of the First Circuit Court of Appeals should be reversed and this Court should determine that the False Claims Act does not create a cause of action for implied certification of compliance.

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